REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1-13 are pending with entry of this amendment. Claim 1 is amended herein. This amendment introduces no new matter and support for the amendment is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to amended claim 1, support for the nuclear transcription factor ligand cognate receptor being different from the estrogen receptor can be found, e.g., at paragraph 14, line 6; the experiment at paragraph 123; and, the experiment at paragraph 126.

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

35 U.S.C. §112, First Paragraph.

Claims 1-13 were rejected under 35 U.S.C. §112, first paragraph, for alleged failure of the specification to support the term "an additional member of the nuclear transcription factor superfamily" in claim 1. However, as this term is removed from the amended claim 1, this rejection is moot.

Claims 1-5 and 8-11 were rejected under 35 U.S.C. §112, first paragraph, for alleged failure of the specification to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the invention. That is, the Examiner alleged that " the large genus of receptors used in the method claimed can not be envisioned by one in the art." This rejection referred to the cognate receptor term in the expression "an additional member of the nuclear transcription factor superfamily, which member of the nuclear transcription factor superfamily comprises a cognate receptor for said nuclear transcription factor ligand ..." However, the expression has been deleted from claim 1, as amended, and the point is therefore moot.

The genus of methods in the currently amended claim 1 is explicitly described in the specification. Such a description is adequate support for a genus, even without the mention of representative species (*Lilly*, 43 USPQ2d at 1406). Generic descriptions of the claimed screening methods are found throughout the specification, e.g., in paragraphs 9, and 40. These generic descriptions are adequate support for the claimed screening method.

Furthermore, the present application provides a representative number of screening method species in the specification, thereby redundantly supporting the claimed invention according to *Lilly*, *Fiers*, and other applicable cases. A variety of specific methods examples are reduced to practice and described for screening various ligands/cognate receptor combinations for modulation of estrogen activation at AP-1 sites. For example, the specification describes screening of combinations, such as: estradiol/GR, dexamethasone/GR, estradiol/PR-A, estradiol/PR-B, dexamethasone/PR-A, dexamethasone/PR-B, progestin/PR-A, and progestinPR-B, using the methods of the invention. The specification describes additional specific examples of cognate receptors (androgen receptor, a mineralcorticoid receptor, and a prostaglandin receptor) that can work in combination with ligands (glucocorticoid, vitamin D, retinoic acid, androgens, and mineralcorticoids) for screening by the methods. This extensive disclosure of representative species ranging across the genus meets the requirements of section 112 and case law.

Claims 1-13 were also rejected (Office Action, part 9) under 35 U.S.C. §112, first paragraph, for allegedly not reasonably providing enablement for estrogen receptors or cognate receptors that are not functional. The Examiner asserts that "until the ligand is known the determination of the function of the receptor is not known and requires undue experimentation to determine the function of the receptor." It must be kept in mind that section 112 requires enablement of the claimed invention. The claimed invention is to methods "of screening a nuclear transcription factor ligand for an ability to modulate estrogen activation at an AP-1 site ...", not to methods of determining the function of a receptor. Although the specification, at paragraph 46, describes assays for screening an orphan receptor for function, this is not presently claimed subject matter in this case. If a cell, as claimed, is provided with a promoter comprising an AP-1 site that regulates expression of a reporter gene, and contacted with a transcription factor ligand and a

compound having AP-1 mediated estrogenic activity, a difference in reporter gene expression will indicate the ligand modulates estrogen activation at the AP-1 site. The ligand will have been screened for an ability to modulate estrogen activation at the AP-1 site, as claimed. If the cognate receptor or estrogen receptor provided in the cell is non-functional, then the ability of the ligand to modulate estrogen activation at the AP-1 site in the presence of functional receptors may not be detected. A lack of false negative results is not claimed in this screening method. No further experimentation is called for by the claim. Therefore, as the screening method invention presently claimed is fully enabled, and Applicant requests the section 112 rejections withdrawn in this case.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

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Respectfully submitted,

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Attachments:

1) A petition to extend the period of response for **3** months;
2) A transmittal sheet;
3) An Applicant's Interview Summary;
4) A fee transmittal sheet; and,
5) A receipt indication postcard.